



CLINEXEL

Your Trusted Partner for Clinical Research & Pharmacovigilance

A full-service Clinical Research Organization providing end-to-end solutions for clinical development, operations, regulatory affairs, medical writing, and pharmacovigilance across India, USA, Europe, and beyond.

Who We Are

CLINEXEL is an agile, customer-focused full-service CRO with presence in India and the USA. We partner with innovative Pharma, Biotech, and Medical Device companies to navigate funding constraints and regulatory complexities.

Our mission: bring much-needed drugs to patients through scientifically rigorous, cost-effective clinical development strategies and high-quality trial execution.



Award-Winning Excellence

2023 Recognition

Best Full-Service CRO for
Clinical Trials in South Asia
by GHP

2024 Recognition

Best Full-Service CRO for
Clinical Trials in South Asia
by GHP

ISO Certified

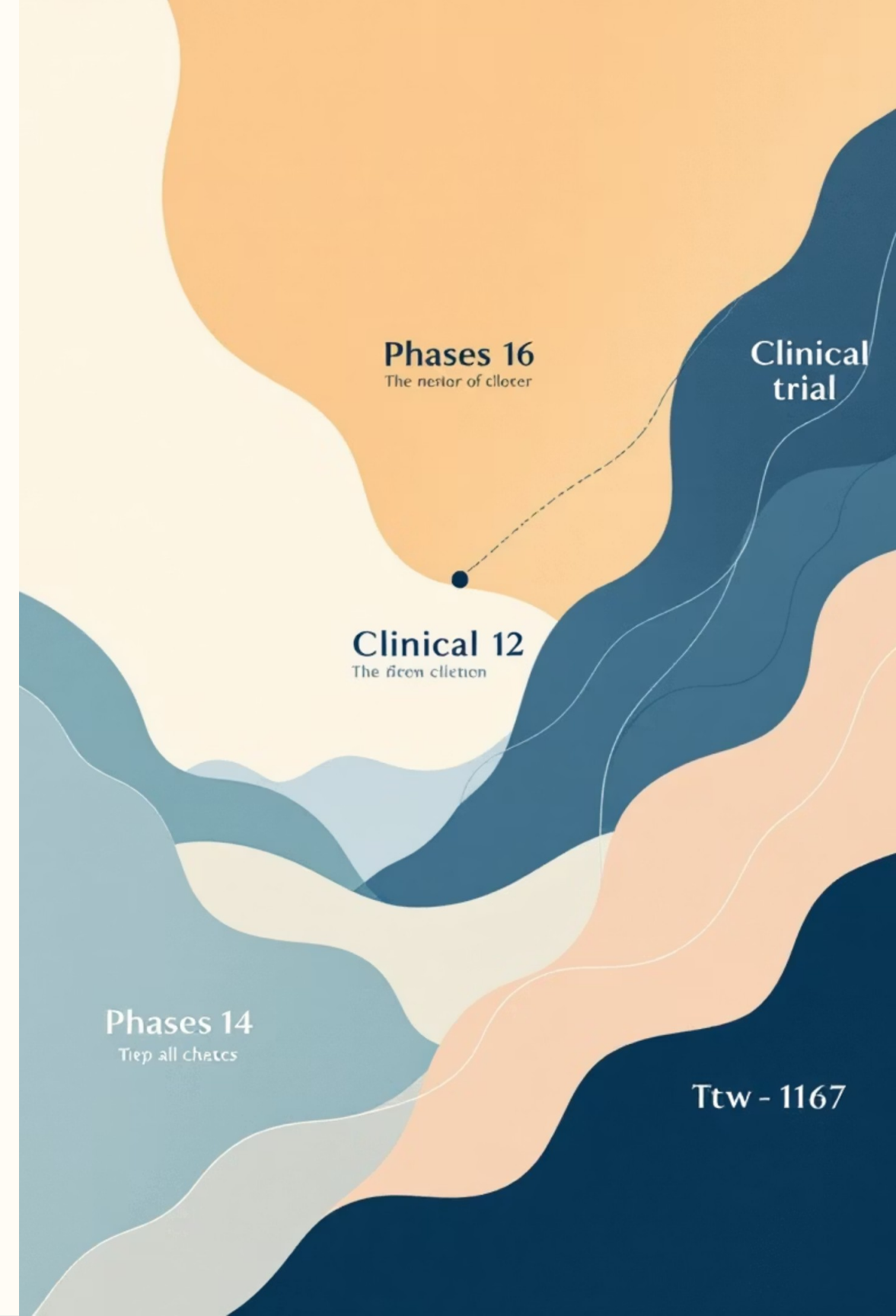
ISO 9001:2015 (QMS) and ISO/IEC 27001:2022 (ISMS)



Proven Track Record

All 4 Clinical Trial Phases

Demonstrated success conducting clinical trials across Phase I-IV, including First in Man studies in both Healthy Volunteers and Patients.



Comprehensive Services



Clinical Trials

Full-service CRO with FTEs providing protocol preparation, regulatory approvals, monitoring, CDM, and CSR writing.



Global Development

Multi-region clinical trials through AICROS alliance with experience across USFDA, MHRA, and European competent authorities.



Regulatory Affairs

CT dossier preparation, CA approvals, pre-IND coordination, IND filings, and agency communication.



Pharmacovigilance

Case processing, regulatory submissions, aggregate reports, literature monitoring, signal detection, RMPs, and QPPV services.



Medical Writing

High-quality protocols, ICFs, IBs, CSRs, CEPs, CERs including literature search and manuscript preparation.



Medical Devices

Pilot and pivotal trials, PMCF studies for CE marking, CEPs, CERs, BEPs, BERs, PEPs, and PERs.

CDSCO Registered CRO

Partner of Choice for Clinical Trials in India

For EU/USA/ROW Registration: CDSCO mandates reasonable percentage of Indian patients in Phase 2/3 trials. If India isn't participating, an additional Phase 3 study in India is required.

For Rare Diseases: Post-marketing clinical trials conducted immediately after marketing license grant.

CLINEXEL as Local CRO: Works with Global CROs for site identification, feasibility, monitoring, regulatory documentation, logistics, and high-quality data collection.



Why Choose CLINEXEL?



Technical Expertise

Senior management with leadership experience in core Pharma, strong understanding of drug development and global regulatory requirements.



Expert Team

GxP expertise, strong regulatory understanding, and experience across various therapeutic areas.



Strong Training

Regular training by senior members, external programs, and updates on new regulations and guidelines.



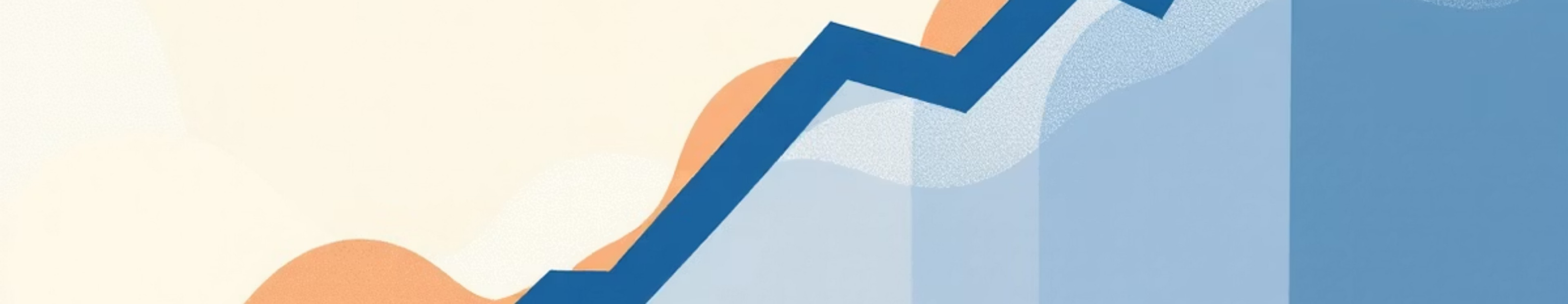
One Stop Solution

End-to-end services with qualified vendors for labs, translations, warehousing, and technology partners for databases and systems.



Scalable Solutions

Rapid scale-up capability through experienced leaders, strong procedures, infrastructure procurement, and process automation.



Cost-Effective Excellence

1

Regulatory Negotiations

Post-marketing commitment optimization through waivers and study design improvements

2

Cost Optimization

Clinical trial waivers, BA/BE studies, and quantitative clinical pharmacology

3

Efficient Design

Protocol optimization and regulatory support following ICH GCP standards and Indian regulations

Global Reach Through AICROS

CLINEXEL is a full member of AICROS (Association of International CROs), an alliance of 8 local and well-established CROs conducting Multi-Region Clinical Trials (MRCTs) worldwide.



MRCTs allow concurrent drug development and approval across various populations, ethnic groups, geographical locations, and regulatory environments.

Let's Connect

Talk to Our Experts

We look forward to discussing your trial management strategy and proposing optimum cost-efficient solutions.

Website: clinexel.com

Email: info@clinexel.com

- India: +91 82913 51946
- USA: +1 (209) 4373929
- UAE: +971 52 382 2824

